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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/875,361	06/05/2001	Su-Chen Chang	20503-2000x-00	7507

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EXAMINER
CHAKRABARTI, ARUN K

ART UNIT	PAPER NUMBER
1634	9

DATE MAILED: 05/02/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/875,361	Chang
Examiner	**Art Unit**
Arun Chakrabarti	1655

-- **The MAILING DATE of this communication appears on the cover sheet with the correspondence address** --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- *Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.*
- *If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.*
- *If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.*
- *Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).*
- *Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).*

Status

1) ☒ *Responsive to communication(s) filed on Jun 5, 2001 .*

2a) ☐ *This action is* **FINAL.** 2b) ☒ *This action is non-final.*

3) ☐ *Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.*

Disposition of Claims

4) ☒ *Claim(s) 1-24 is/are pending in the application.*

4a) *Of the above, claim(s) _____ is/are withdrawn from consideration.*

5) ☐ *Claim(s) _____ is/are allowed.*

6) ☒ *Claim(s) 1-24 is/are rejected.*

7) ☐ *Claim(s) _____ is/are objected to.*

8) ☐ *Claims _____ are subject to restriction and/or election requirement.*

Application Papers

9) ☐ *The specification is objected to by the Examiner.*

10) ☐ *The drawing(s) filed on _____ is/are objected to by the Examiner.*

11) ☐ *The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.*

12) ☐ *The oath or declaration is objected to by the Examiner.*

Priority under 35 U.S.C. § 119

13) ☐ *Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).*

a) ☐ *All* b) ☐ *Some** c) ☐ *None of:*

1. ☐ *Certified copies of the priority documents have been received.*
2. ☐ *Certified copies of the priority documents have been received in Application No. _____ .*
3. ☐ *Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).*

**See the attached detailed Office action for a list of the certified copies not received.*

14) ☐ *Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).*

Attachment(s)

15) ☒ *Notice of References Cited (PTO-892)*

16) ☐ *Notice of Draftsperson's Patent Drawing Review (PTO-948)*

17) ☐ *Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____*

18) ☐ *Interview Summary (PTO-413) Paper No(s). _____*

19) ☐ *Notice of Informal Patent Application (PTO-152)*

20) ☐ *Other:*

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 16-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 is rejected over the recitation of the phrase, "massive amount". The term "massive" in claim 16 is a relative term which renders the claim indefinite. The term "massive" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-9, 11, 16-19, and 22-24 are rejected under 35 U.S.C. 103(a) over Chang et al. (U.S. Patent 5,753,692) (May 19, 1998) in view of Vermeulin et al. (U.S. Patent 6,172,261 B1) (January 9, 2001).

Chang et al teach homogeneous fractions or components obtained from herbs by fractionating an extract of the herb by applying HPLC (Column 3, lines 46-60).

Chang et al teach fractions or components obtained from herbs contain secondary metabolites of a herb (Column 1, line 48 to Column 2, line 2).

Chang et al do not teach a chip comprising a plastic slide, a coating as a spacer on the plastic slide and fractions or components independently allocated in microarrays on the coating.

Vermeulin et al. teach a chip comprising a plastic slide, a coating as a spacer on the plastic slide and fractions or components independently allocated in microarrays on the coating (Column 31, lines 6-42).

Chang et al do not teach a chip, wherein the material of the plastic slide is a copolymer made of ethylene, propylene or styrene.

Vermeulin et al. teach a chip, wherein the material of the plastic slide is a copolymer made of ethylene, propylene or styrene (Column 31, lines 6-14).

Chang et al do not teach a chip, wherein the plastic slide is made of two cavity chambers.

Vermeulin et al. teach a chip, wherein the plastic slide is made of two cavity chambers (Column 31, lines 35-42) (microplates in this case).

Chang et al do not teach a chip, wherein the coating is made of polyfunctional molecules.

Vermeulin et al. teach a chip, wherein the coating is made of polyfunctional molecules (Abstract and Column 33, lines 30-67 and Figures 29-31) (polyamine in this case).

Chang et al do not teach a method of producing the chip, comprising the steps of preparing a plastic slide, coating the surface of the plastic slide with polyfunctional molecules, and spotting and immobilizing on the coated plastic slide a massive amount of samples in a gridded area in microarrays, wherein each sample contains fractions or ingredients obtained from the herb.

Vermeulin et al. teach a method of producing the chip, comprising the steps of preparing a plastic slide, coating the surface of the plastic slide with polyfunctional molecules, and spotting and immobilizing on the coated plastic slide a massive amount of samples in a gridded area in microarrays, wherein each sample contains fractions or ingredients (Column 33, line 30 to Column 38, line 15).

Chang et al do not teach a method, wherein the samples are spotted or immobilized on the surface of cavity chambers.

Vermeulin et al. teach a method, wherein the samples are spotted or immobilized on the surface of cavity chambers (Column 35, lines 2-36).

Chang et al do not teach a method, wherein the plastic slide is pretreated with a polyfunctional aldehyde glutaraldehyde followed by soaking in a solution of NH2 groups-providing precursor before coating the plastic slide.

Vermeulin et al. teach a method, wherein the plastic slide is pretreated with a polyfunctional aldehyde glutaraldehyde followed by soaking in a solution of NH2 groups-providing precursor before coating the plastic slide (Column 33, lines 49-52).

Chang et al do not teach a method of using the chip for screening for active ingredients in herbs, comprising the steps of loading a labeled probe(s)-containing solution onto the chip for conducting hybridization, and imaging and identifying the gridded samples that react with or bind to the labeled probe.

Vermeulin et al. teach a method of using the chip for screening for active ingredients in target pharmaceutical composition, comprising the steps of loading a labeled probe(s)-containing solution onto the chip for conducting hybridization, and imaging and identifying the gridded samples that react with or bind to the labeled probe (Column 33, line 49 to Column 38, line 15).

Chang et al do not teach a method, wherein the labeled probe(s)-containing solution is heterogeneous.

Vermeulin et al. teach a method, wherein the labeled probe(s)-containing solution is heterogeneous.(Column 33, lines 60-67).

Chang et al do not teach a method, wherein the label is a dye.

Vermeulin et al. teach a method, wherein the label is a dye (Column 34, lines 14-19).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute the chip containing polyamine analogues as therapeutic and diagnostic agents of Vermeulin et al. in the method of extraction of medicinal herbal compounds of Chang et al. since Vermeulin et al. state, "The assays of the invention are useful for high throughput screening of targets in the discovery of drugs that interact with the polyamine system (Abstract, last sentence)." An ordinary practitioner would have been motivated to combine and substitute the chip containing polyamine analogues as therapeutic and diagnostic agents of Vermeulin et al. in the method of extraction of medicinal herbal compounds of Chang et al., in order to achieve the express advantage, as noted by Vermeulin et al, of the assays of the invention, which are useful for high throughput screening of targets in the discovery of drugs that interact with the polyamine system.

5. Claims 1-11, 16-20, and 22-24 are rejected under 35 U.S.C. 103(a) over Chang et al. (U.S. Patent 5,753,692) (May 19, 1998) in view of Vermeulin et al. (U.S. Patent 6,172,261 B1) (January 9, 2001) further in view of Gerster (U.S. Patent 5,714,608) (February 3, 1998).

Chang et al. in view of Vermeulin et al teach herbal chip and method of claims 1-9, 11, 16-19, and 22-24 as described above.

Chang et al. in view of Vermeulin et al do not teach ammonium hydroxide as NH2 group(s)-providing precursor.

Gerster teach ammonium hydroxide as NH2 group(s)-providing precursor (Column 7, lines 21-34 and Column 8, lines 31-54).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute the ammonium hydroxide as NH2 group(s)-providing precursor of Gerster in the herbal chip and method of Chang et al in view of Vermeulin et al. since Gerster states, "Suitable amminating agents include ammonia (e.g., in the form of ammonium hydroxide) and ammonium salts (e.g., ammonium carbonate, ammonium bicarbonate, and ammonium phosphate). Ammonium hydroxide is preferred (Column 8, lines 43-47)." An ordinary practitioner would have been motivated to combine and substitute the ammonium hydroxide as NH2 group(s)-providing precursor of Gerster in the herbal chip and method of Chang et al in view of Vermeulin et al., in order to achieve the express advantage, as noted by Gerster, of the suitable amminating agents including ammonia (e.g., in the form of ammonium hydroxide) and ammonium salts (e.g., ammonium carbonate, ammonium bicarbonate, and ammonium phosphate), wherein ammonium hydroxide is preferred.

6. Claims 1-9, 11-19, and 21-24 are rejected under 35 U.S.C. 103(a) over Chang et al. (U.S. Patent 5,753,692) (May 19, 1998) in view of Vermeulin et al. (U.S. Patent 6,172,261 B1) (January 9, 2001) further in view of Cruickshank (U.S. Patent 6,194,563 B1) (February 27, 2001).

Chang et al. in view of Vermeulin et al teach herbal chip and method of claims 1-9, 11, 16-19, and 22-24 as described above.

Chang et al. in view of Vermeulin et al do not teach polyfunctional epoxide on the chip that can react with hydroxyl, sulfhydryl or amino groups.

Cruickshank teaches polyfunctional epoxide on the chip that can react with hydroxyl, sulfhydryl or amino groups (Column 7, line 58 to column 8, line 21).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine and substitute the polyfunctional epoxide on the chip that can react with hydroxyl, sulfhydryl or amino groups of Cruickshank in the herbal chip and method of Chang et al in view of Vermeulin et al. since Cruickshank states, "Surfaces can be functionalized with, for example, amino, sulfhydryl, hydroxyl or epoxide reactive groups that subsequently can be used to attach biochemical ligands to the surface (Column 7, lines 63-66)." An ordinary practitioner would have been motivated to combine and substitute the polyfunctional epoxide on the chip that can react with hydroxyl, sulfhydryl or amino groups of Cruickshank in the herbal chip and method of Chang et al in view of Vermeulin et al. in order to achieve the express advantage, as noted by Cruickshank, of the surfaces functionalized with, for example, amino, sulfhydryl, hydroxyl or epoxide reactive groups that subsequently can be used to attach biochemical ligands (obviously present in herbs) to the surface.

Chang et al. in view of Vermeulin et al. further in view of Cruickshank do not teach the polyfunctional epoxide containing a long chain of 6 to 24 carbon atoms. However, it is *prima*

facie obvious that selection of a particular length of carbon atoms in an epoxide molecule in a pharmaceutical composition represents routine optimization with regard to the requirement of the biochemical ligands to be attached to the surface of the chip, which routine optimization parameters are explicitly recognized to an ordinary practitioner in the relevant art. As noted *In re Aller*, 105 USPQ 233 at 235,

> More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.

Routine optimization is not considered inventive and no evidence has been presented that the selection of a particular length of carbon atoms in an epoxide molecule in a pharmaceutical composition was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art.

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D., whose telephone number is (703) 306-5818. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703) 308-1152.Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196. Papers related to this application may be submitted to

Technology Center 1600 by facsimile transmission via the P.T.O. Fax Center located in Crystal Mall 1. The CM1 Fax Center numbers for Technology Center 1600 are either (703) 305-3014 or (703) 308-4242. Please note that the faxing of such papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Arun Chakrabarti
Patent Examiner
Art Unit 1634

April 15, 2002

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600